

Inspection is defined as the evaluation by observation and judgment accompanied as appropriate by measurement, testing or gauging of the conformity of a product, process or service to specified requirements.

NIST means the National Institute of Standards and Technology, an agency within the United States Department of Commerce.

Recognition means a procedure used to provide formal notice that an accreditation body is competent to carry out specific tasks. These tasks include: the accreditation of testing laboratories and inspection, certification, and registration bodies. A governmental recognition system is a set of one or more procedures used by a Federal agency to provide recognition.

Registration means a procedure used to give written assurance that a system conforms to specified requirements. Such systems include those established for the management of product, process or service quality and environmental performance.

Sampling means the selection of one or more specimens of a product, process, or service for the purpose of evaluating the conformity of the product, process or service to specified requirements.

Supplier's declaration of conformity means a procedure by which a supplier gives written assurance that a product, process, service or organization conforms to specified requirements.

Testing means the action of carrying out one or more technical operations (tests) that determine one or more characteristics or performance of a given product, material, equipment, organism, person's qualifications, physical phenomenon, process, or service according to a specified technical procedure (test method).

§ 287.3 Responsibilities of the National Institute of Standards and Technology.

(a) Work with agencies through the Interagency Committee on Standards Policy (ICSP) to coordinate Federal, state and local conformity assessment activities with private sector conformity assessment activities. NIST chairs the ICSP; assists the ICSP in developing and publishing policies and

guidance on conformity assessment related issues; collects and disseminates information on Federal, state and private sector conformity assessment activities; and increases public awareness of the importance of conformity assessment and nature and extent of national and international conformity assessment activities.

(b) Encourage participation in the ICSP by all affected agencies and ensure that all agency views on conformity assessment are considered.

(c) To the extent that resources are available, develop information on state conformity assessment practices; and, upon request by a state government agency, work with that state agency to reduce duplication and complexity in state conformity assessment activities.

(d) Review within three years from August 10, 2000, the effectiveness of the final guidance and recommend modifications to the Secretary as needed.

§ 287.4 Responsibilities of Federal agencies.

Each agency should:

(a) Implement the policies contained in the guidance in this part.

(b) Provide a rationale for its use of specified conformity assessment procedures and processes in rulemaking and procurement actions to the extent feasible. Further, when notice and comment rulemaking is otherwise required, each agency should provide the opportunity for public comment on the rationale for the agency's conformity assessment decision.

(c) Use the results of other governmental agency and private sector organization conformity assessment activities to enhance the safety and efficacy of proposed new conformity assessment requirements and measures. An example of this would be to collect and review information on similar activities conducted by other Federal, state and international organizations and agencies and private sector organizations to determine if the results of these activities can be used to improve the effectiveness of a proposed Federal agency conformity assessment activity.

(d) Use relevant guides or standards for conformity assessment practices

§ 287.4

published by domestic and international standardizing bodies as appropriate in meeting regulatory and procurement objectives. Guides and standards for sampling, testing, inspection, certification, quality and environmental management systems, management system registration and accreditation are issued by organizations which include, but are not limited to, the American National Standards Institute, the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), the International Telecommunications Union (ITU) and the Organization for Economic Cooperation and Development (OECD), the World Health Organization (WHO), and the Codex Alimentarius Commission. Each agency retains responsibility for determining which, if any, of these documents are relevant to its needs.

(e) Identify appropriate private sector conformity assessment practices and programs and consider the results of such practices and/or programs as appropriate in existing regulatory and procurement actions. Responsibility for the determination of appropriateness rests with each agency. Examples: an agency could use the results of private sector or other governmental conformity assessment activities to schedule procurement type audits more effectively. This could allow agencies to reduce the number and extent of audits conducted at companies which are performing in accordance with contract specifications and which are under review by a third party or another agency and to concentrate agency audit efforts on companies which have shown problems in conforming to contract specifications. Another example is the Federal Communications Commission's (FCC) Telecommunication Certification Body (TCB) program, which allows designated private entities to issue telecommunications equipment approvals for specified regulatory requirements. In addition, under Part 15, FCC premarketing approval requirements for certain types of equipment have been replaced with suppliers declaration of conformity to the regulations, provided test results supporting the declaration are obtained from an accredited testing lab.

15 CFR Subtitle B, Ch. II (1-1-03 Edition)

(f) Consider using the results of other agencies' conformity assessment procedures. Example: An agency could use the results of another agency's inspection/audit of a supplier to eliminate or reduce the scope of its own inspection/audit of that supplier.

(g) Participate in efforts designed to improve coordination among governmental and private sector conformity assessment activities. These efforts include, but are not limited to, the National Cooperation for Laboratory Accreditation (NACLA) organization, the National Environmental Laboratory Accreditation (NELAC), the International Organizations for Standardization's (ISO) Committee on Conformity Assessment (CASCO), conformity assessment related activities of the American National Standards Institute (ANSI), and ICSP working groups dealing with conformity assessment issues.

(h) Work with other agencies to avoid unnecessary duplication and complexity in Federal conformity assessment activities. Examples: An agency can participate in another agency's conformity assessment activities by conducting joint procurement audits/inspections of suppliers that sell to both agencies. An agency can share conformity assessment information with other agencies. An agency can use conformity assessment information provided by other agencies to the extent appropriate to improve the effectiveness and efficiency in its own conformity assessment activities. Conformity assessment information may include: Conformity assessment procedures and results, technical data on the operation of conformity assessment programs, processing methods and requirements for applications, fees, facility site data, complaint review procedures, and confidentiality procedures.

(i) Encourage domestic and international recognition of U.S. conformity assessment results by supporting the work of the U.S. Government in international trade and related negotiations with foreign countries and U.S. industry in pursuing agreements with foreign national and international private sector organizations and any

resulting activities/requirements resulting from those negotiations/agreements.

(j) Participate in the development of private sector conformity assessment standards to ensure that Federal viewpoints are represented.

(k) Work with other agencies to harmonize Federal requirements for quality and environmental management systems for use in procurement and regulation, including provisions which will allow the use of one quality or environmental management system per supplier facility in the Federal procurement process and the sharing and usage of audit results and related information as appropriate.

(l) Work with other ICSP members, NIST, and the private sector to develop national infrastructures for coordinating and harmonizing U.S. conformity assessment needs, practices and requirements in support of the efforts of the U.S. Government and U.S. industry to increase international market access for U.S. products.

(m) Work with other ICSP members, NIST, and the private sector as necessary and appropriate to establish criteria for the development and implementation of governmental recognition systems to meet government recognition requirements imposed by other nations and regional groups to support the efforts of the U.S. Government to facilitate international market access for U.S. products.

(n) Assign an Agency Standard Executive responsibility for coordinating the agency-wide implementation of the guidance in this part.

§ 287.5 Responsibilities of an Agency Standards Executive.

In addition to carrying out the duties described in OMB Circular A-119 re-

lated to standards activities, an Agency Standards Executive should:

(a) Promote the following goals:

(1) Effective use of agency conformity assessment related resources and participation in conformity assessment related activities of agency interest.

(2) Development and dissemination of agency technical and policy positions.

(3) Development of agency positions on conformity assessment related issues that are in the public interest.

(b) Ensure that agency participation in conformity assessment related activities is consistent with agency missions, authorities, priorities, and budget.

(c) Cooperate with NIST in carrying out agency responsibilities under the guidance in this part.

(d) Consult with NIST, as necessary, in the development and issuance of internal agency procedures and guidance implementing the policies in this part.

(e) Establish an ongoing process for reviewing his/her agency's existing conformity assessment activities and identifying areas where efficiencies can be achieved through coordination with other agency and private sector conformity assessment activities.

(f) Work with other parts of his/her agency to develop and implement improvements in agency conformity assessment related activities.

(g) Report to NIST, on a voluntary basis, on agency conformity assessment activities for inclusion in the annual report to the Office of Management and Budget (OMB) on the agency's implementation of OMB Circular A-119.